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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,623	01/28/2002	Gary E. Rehm	MSE #2620	9413

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EXAMINER	
RAMILLANO, LORE JANET	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/056,623	REHM, GARY E.	
	Examiner	Art Unit	
	LORE RAMILLANO	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/21/08 has been entered.

Status of Claims

2. In applicant's reply filed on 8/21/08, applicant amended claims 1, 8, and 15. Claims 29-43 are cancelled. Claims 1-28 are pending.

Prior art rejections

3. The rejections over the prior art are maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. **Claims 1, 2, 8, 9, 15, 16, and 23-28** are rejected under 35 U.S.C. 102(b) as being anticipated by Howard et al. ("Howard '341," US 5945341).

As to claims 1 and 2, Howard '341 teaches a method of using an infrared reading to detect the misidentification of a diagnostic test strip, having a plurality of marker fields (i.e. 504a, b, and c) configured to reflect light in a manner correlated to identification of the test strip (i.e. col. 4, lines 5-16), and having a plurality of test pads separate from the marker fields (i.e. col. 3, lines 47-59), the test pads having reagents thereon (i.e. (i.e. col. 3, lines 47-59), the method comprising the steps of:

identifying the test strip by reading reflectances of one or more of the plurality of marker fields (i.e. col. 4, lines 2-16);

determining if the infrared reflectance of one or more of the plurality of test pads is within an acceptable predetermined range (i.e. col. 3, lines 52-58);

determining that the test strip is misidentified in the event the infrared reflectance of one or more of the plurality of test pads is outside of the acceptable predetermined range;

aborting the test if said infrared reflectances are not within said range; and said reagent is leukocyte (i.e. col. 4, lines 26-34; col. 5, lines 9-15; and col. 8, line 49 to col. 9, line 8).

As to claims 8 and 9, Howard '341 teaches an automated method of using an infrared reading to detect the misidentification of a diagnostic test strip disposed on a feed table comprising the steps of:

determining if the test strip possesses specified reagents on the plurality of test pads;

locating the position of plurality of test pads on said strip;

reading the infrared reflectances from each of the plurality of test pads;

determining if said infrared reflectances are within an acceptable predetermined range; determining that said test strip is misidentified in the event of said infrared reflectances are outside of the acceptable predetermined range; aborting said method if said infrared reflectances for one or more of said reagents are not within said predetermined range; and said reagents are leukocyte (i.e. col. 4, line 16 to col. 5, line 15; and col. 8, line 49 to col. 9, line 8).

As to claims 15, 16, and 23-28, Howard '341 teaches an automated method of reading a test strip comprising: (a) providing a test strip having a plurality of test fields on its surface that reflects light at a specific range of wavelengths and at least two distinct marker fields on the same surface of the test strip as the test fields, the marker fields reflecting light at different ranges of wavelengths from each other and from the test fields in a coded sequence of ranges of wavelengths;

(b) introducing the test strip into a strip reading device equipped with a reading means for both the test fields and the marker fields, the reading means comprises a light source as a transmitter and a light sensitive element as receiver, the receiver being capable of differentiating between the ranges of wavelengths at which the test fields and the marker fields reflect, the strip reading device also being equipped with means for correlating the coded range of infrared wavelength sequence of reflected light with preprogrammed information concerning the test strip, the correlating means being in operative communication with a receiving means, the reading device having means for moving the test strip and the receiving means relative to one another so that the reflectance of the test fields and the marker fields can be individually read by the reading means;

(c) allowing the ranges of wavelengths values reflected by the test fields and the marker fields to be individually read by the reading means; (d) allowing the reading means to communicate the coded infrared sequence of spectral reflectance values reflected from the marker fields to the correlating means and allowing the correlating means to correlate the infrared sequence of reflected range of wavelength values with the preprogrammed information concerning the test strip; (e) allowing the reading means to communicate the reflected range of infrared wavelength values to the correlating means and allowing the correlating means to determine for one or more of the reagents disposed on the test strip; and determining that the test strip is misidentified in the event the infrared reflectances from the test fields are outside of the predetermined range (figs. 1-

8a, i.e. column 3, line 34 to column 11, line 56; and col. 8, line 49 to col. 9, line 8).

Howard '341 further teaches the following: the test strip is placed on a feed table (fig. 2); the reagents comprise leukocyte; the range of wavelength value reflected from the test field and the marker fields are read by moving the test strip and the reading means relative to each other; the feed table is movable in relation to the reading means; the reading means is capable of acquiring spatial and spectral reflectances across the length of the test strip; the information concerning said test strip is calibration information based on the particular batch from which said test strip was obtained; the information concerning said test strip relates to location of reactive areas, critical times, strip age and strip reactivity; and the marker fields comprise bars that are substantially parallel to each other and are substantially perpendicular to the longitudinal axis of the test strip (i.e. column 12, lines 30-56).

6. **Claims 1-3, 5, 7-10, 12, and 14** are rejected under 35 U.S.C. 102(e) as being anticipated by Corey et al. ("Corey," US 6316264).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As to claims 1-3, 5 and 7, Corey teaches a method of using infrared reading to detect the misidentification of a diagnostic test strip, having a plurality of marker fields (i.e. col. 10, lines 13-20) configured to reflect light in a manner correlated to identification of the test strip, and having a plurality of test pads separate from the marker fields, the test pads having reagents thereon (i.e. col. 5, line 63 to col. 5, line 7), the method comprising the steps of:

identifying the test strip by reading reflectances of one or more of the plurality of marker fields (i.e. col. 4, lines 2-16);

determining if the infrared reflectance of one or more reagents is within an acceptable predetermined range; determining that the test strip is misidentified in the event the infrared reflectance of one or more reagents is outside of the acceptable predetermined range; the step of aborting the test if the infrared reflectances are not within the range; the reagents are leukocyte, glucose and albumin; the predetermined infrared reflectance range of glucose reagent is from 75 to about 95 percent infrared reflectance; and the test will be aborted if the test strip is more than about 0.02 inches from a central location on a feed table or if the test strip is incompletely inserted by more than about 0.05 inches (i.e. column 3, lines 41-54; column 7, line 9 to column 8, line 62; column 13, lines 19-27; column 14, lines 8-20; column 16, lines 13-23; column 18, lines 60-63).

As to claims 8-10, 12, and 14, Corey teaches an automated method of using an infrared reading comprising the step of: determining if the test strip possess specified reagents, locating the position of the reagents on the strip; reading the infrared reflectances from the reagent positions; determining if the

infrared reflectances are within an acceptable predetermined range; determining that the test strip is misidentified in the event the one or more reagents are outside of the acceptable predetermined range; the step of aborting the test if the infrared reflectances are not within the range; the reagents are leukocyte, glucose and albumin; the predetermined infrared reflectance range of glucose reagent is from 75 to about 95 percent infrared reflectance; and the test will be aborted if the test strip is more than about 0.02 inches from a central location on a feed table or if the test strip is incompletely inserted by more than about 0.05 inches (i.e. column 3, lines 41-54; column 7, line 9 to column 8, line 62; column 13, lines 19-27; column 14, lines 8-20, column 16, lines 13-23; column 18, lines 60-63).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 4, 6, 11, 13, and 18-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard '341.

The teachings of Howard are indicated above. While Howard '341 teaches a method comprising reagents to analyze analytes, such as leukocytes; aborting the test if an error arises; and means for correlating spectral reflectance values at each spectral region of reflected light with preprogrammed information concerning the test strip; Howard '341 does not specifically teach a method comprising glucose and albumin reagents; a predetermined infrared reflectance range of the leukocyte reagent is from about 57.0 to about 73.0 percent infrared

reflectance; a predetermined infrared reflectance range of albumin reagent is from about 60.0 to about 75.0; and aborting the test if the test strip is more than about 0.2 inches from a central location.

It would have been obvious to a person of ordinary skill in the art to include the analysis of analytes, such as glucose and albumin, into the invention of Howard '341 since Howard '341 acknowledges this his system is capable of analyzing different types of analytes, such as glucose and albumin, and it would be desirable to have a system that is capable analyzing more than one type of analyte.

With regard to having predetermined infrared reflectance ranges for leukocyte and albumin, it would have been obvious to a person of ordinary skill in the art to input such predetermined information into the automated system of Howard '341 because it would be beneficial to have a system that can easily and quickly identify the analyte on the test strip, move the test strip to the proper location, and collect data at the proper wavelengths and at the proper time or times such that the collected data can be analyzed by an appropriate algorithm to complete the assay (Howard '341, column 6, lines 51-63).

With regard to aborting the test if the test strip is more than about 0.2 inches from a central location, it would have been obvious to a person of ordinary skill in the art to terminate the test if any error occurs during the analysis of the test strip to insure that the test results are accurate and reliable.

9. **Claims 15-17, 23-25, and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard et al. ("Howard '803," US 5654803) in view of Howard '341.

Howard '803 teaches an automated method of reading a test strip comprising: (a) providing a test strip (fig. 2) having at least one test field on its surface that reflects light at a specific range of wavelengths and at least two distinct marker fields on the same surface of the test strip as the test field, the marker fields reflecting light at different ranges of wavelengths from each other and from the test field in a coded sequence of ranges of wavelengths (i.e. fig. 5, column 4, line 55 to column 5, line 47); (b) introducing the test strip into a strip reading device (fig. 1) equipped with a reading means for both the test field and the marker fields, the reading means comprises a light source (46, fig. 3) as a transmitter and a light sensitive element as receiver (fig. 4), the receiver being capable of differentiating between the ranges of wavelengths at which the test field and the marker fields reflect, the strip reading device also being equipped with means for correlating the coded range of infrared wavelength sequence of reflected light with preprogrammed information concerning the test strip, the correlating means being in operative communication with a receiving means (figs. 6-7, i.e. column 6, line 36 to column 7, line 62), the reading device having means for moving the test strip and the receiving means relative to one another so that the reflectance of the test field and the marker fields can be individually read by the reading means (means for moving, i.e. column 6, lines 49-54); (c) allowing the ranges of wavelengths values reflected by the test field and the

marker fields to be individually read by the reading means; (d) allowing the reading means to communicate the coded infrared sequence of spectral reflectance values reflected from the marker fields to the correlating means and allowing the correlating means to correlate the infrared sequence of reflected range of wavelength values with the preprogrammed information concerning the test strip; and (e) allowing the reading means to communicate the reflected range of infrared wavelength values to the correlating means and allowing the correlating means to determine for one or more of the reagents disposed on the test strip (figs. 6-7, i.e. column 6, line 36 to column 7, line 62).

Howard '803 further teaches the following: the test strip is placed on a feed table (20, fig. 2); the reagents comprise leukocyte, glucose and albumin (i.e. column 3, lines 41-54); the range of wavelength value reflected from the test field and the marker fields are read by moving the test strip and the reading means relative to each other (i.e. column 4, lines 1-8); the feed table is movable in relation to the reading means (i.e. column 4, lines 1-8); the reading means is capable of acquiring spatial and spectral reflectances across the length of the test strip (i.e. fig. 3); and the marker fields comprise bars that are substantially parallel to each other and are substantially perpendicular to the longitudinal axis of the test strip (i.e. fig. 5).

Howard '803 does not specifically teach the step of determining if a test strip is misidentified.

The teaching of Howard '341 is indicated above. It would have been obvious to a person of ordinary skill in the art to modify Howard '803 in view of

Howard '341 because it would be desirable to have a method of determining whether a test strip is misidentified to insure the test results produced from a test strip are accurate.

Response to Arguments

10. Applicant's arguments, see p. 8-13, filed 8/21/08, have been fully considered but they are not persuasive.

Howard '341 rejection

In response to applicant's argument that Howard '341 does not disclose having multiple test fields, examiner respectfully disagrees. As indicated above, Howard '341 discloses multiple test fields on col. 3, lines 47-58.

In response to applicant's argument that Howard '341 does not disclose that it determines whether it is within an acceptable range, examiner respectfully disagrees. Howard '341 discloses in col. 3, lines 47-58 this limitation.

In response to applicant's argument that Howard '341 does not disclose determining whether the strip has been misidentified, based on the infrared reflectances of the reagent (test) fields, as claimed, examiner respectfully disagrees. Howard '341 teaches this step in, for example, col. 8, line 49 to col. 9, line 7. In this cited disclosure, it appears that the infrared reflectances of the test region (501, fig. 2) are measured to determine, i.e. whether an error occurred. This "error" inherently refers to a misidentification of the of the test strip since Howard '341 specifically teaches in col. 1, lines 6-8 that his invention is concerned with the method of optical identification of test strips. Furthermore, applicant should note that the pending claims may be given their broadest

reasonable interpretation consistent with the specification. Thus, it appears that Howard '341 reads on the recited claim language.

Corey rejection

In response to applicant's argument that Corey does not disclose the claimed step of identifying the test strip by reading reflectances of one or more of the plurality of marker fields, examiner respectfully disagrees. The pending claims may be given their broadest reasonable interpretation consistent with the specification. Based on the disclosure of Corey, it appears that Corey "identifies" the test strip by reading reflectances because the detection apparatus must detect or identify the IR dye for the test strip to determine, i.e. the test strip's alignment properties.

In response to applicant's argument that Corey does not disclose determining if a test strip is misidentified based on infrared reflectances of test/reagent areas are within an acceptable predetermined range, examiner respectfully disagrees. Corey teaches the step of determining whether a test strip is misidentified in, for example, column 14, lines 8-20. In this cited disclosure, Corey teaches colored test strips that were determined to be misidentified (i.e. false positive or false negative test assays) based on the infrared reflectance of the reagent areas.

35 USC 103(a) rejections

It appears that applicant's arguments under the 35 USC 103(a) rejection section are based on the arguments indicated above. Therefore, examiner will maintain the basis of rejections for the reasons indicated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE RAMILLANO whose telephone number is (571)272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1797

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